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10/508,398	05/10/2005	Craig Gregory Smith	18155-002US1	9329
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FISH & RICHARDSON, PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022				
EXAMINER				
RAPILLO, KRISTINE K				
ART UNIT		PAPER NUMBER		
3626				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

# Office Action Summary

**Application No.**

10/508,398

**Applicant(s)**

SMITH ET AL.

**Examiner**

KRISTINE K. RAPILLO

**Art Unit**

3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 September 2009.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-23 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 20 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO/S5-08)  
Paper No(s)/Mail Date 9/20/2004; 1/22/2007  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

**Notice to Applicant**

1. This communication is in response to the amendment filed September 8, 2009. Claims 1, 7, 10 – 13, 16 – 18, and 23 are amended. Claims 1 - 23 are pending.

***Claim Rejections - 35 USC § 112***

2. The 35 U.S.C. 112, second paragraph rejections of claims 1 and 23 are hereby withdrawn based upon the amendment submitted September 8, 2009.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1 – 6 and 8 – 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richardson et al., herein after Richardson (U.S. Publication Number 2003/0225596 A1) in view of Frederick (U. S. Patent Number 6,788,997), further in view of Newton et al., herein after Newton (U.S. Patent Number 7,467,093).

With regard to claim 1 (Currently Amended), Richardson teaches a computerised identity matching management process for the supply of a pharmaceutical substance to an authorised patient, the process comprising the steps of:

a management computer receiving a request, from capture apparatus waiting to commence a biometric capture process representative of the patient to initiate the capture process (paragraphs 32 and 60 where a provider (i.e. physician, nurse) carries or wears and identification key with their biometric identity stored on it. The key will activate a biometric scanner within a certain distance of the scanner.

The provider, using a biometric scanner, will scan in; if the identification key and the new scan match up the user is allowed access. Thus, the request is equated to the identification key activating the biometric scanner);

the management computer responding to the request to return a message to the capture apparatus at a first time (paragraphs 28, 30, 57, and 58), the message containing a unique code (paragraphs 28, 30, 57, and 58), and where receipt of the message containing the code at the capture apparatus causes initiation of the capture process (paragraphs 28, 30, 57, and 58);

the management computer, after returning the message, receiving a captured biometric representative of the patient from the capture apparatus coded with the code, at a second time (paragraphs 32, 57, and 58); and

the management computer operating, when the second time is less than a predetermined time later than the first time (paragraphs 28, 32, and 58), to decode the captured biometric (paragraphs 28 and 32 where decode is equated to reading the biometric scan) and initiate a matching process to find a match for the decoded captured biometric against stored biometric records and to retrieve an identification code representative of the patient when a match is found (paragraphs 30 and 32).

Frederick teaches a process comprising:

retrieving a date stamp and using the identification code to retrieve a stored data record of the patient which includes at least a substance the patient is prescribed, a quantity in which the substance is to be supplied and a date at which the substance is to be supplied (Figure 30; column 20, lines 29 – 43; column 42, lines 6 – 12; and column 56, lines 45 – 60);

determining whether the date stamp matches the date at which the substance is to be supplied (Figure 30; column 20, lines 29 – 43; column 42, lines 6 – 12; and column 56, lines 45 – 60), and

if a match is determined, supplying the substance in the prescribed quantity and recording information to form a record to update the supply of the substance to the patient (Figure 39; column 9, lines 38 – 59; column 42, lines 66 – 67; column 43, lines 44 – 61; and column 46, lines 48 – 65).

Newton teaches a process identifying a patient who is requesting the supply of the substance (Abstract and column 5, lines 36 – 57) where the user requesting the substance or medication may be a health care provider or a patient.

Richardson teaches a biometric method for controlling access to and tracking usage of medication using biometric scanning of health care providers. Newton teaches a method of tracking and dispensing medical items to a patient through self-service delivery system

The sole difference between the primary reference (Richardson) and the claimed subject matter is that the primary reference does not disclose the biometric authorization of a patient; the primary reference authenticates a health care provider via a biometric device. The secondary reference (Newton) discloses the biometric authentication of a patient for drug dispensing.

The secondary reference show that biometric authentication of a patient for self service drug dispensing was known in the art at the time of the invention. Since each individual element and it's function are shown in the prior art, albeit shown in separate references, the difference between the claimed subject matter and the prior art rests not on any individual element or function but in the very combination itself – that is in the substitution of the patient for the health care provider of the primary reference.

Thus, the simple substitution of one known element for another producing a predictable result renders the claim obvious.

With regard to claim 2 (Original), Richardson, Frederick, and Newton teach the process according to claim 1. Richardson teaches a process where the biometric records are securely stored within the management computers cache (paragraphs 13 and 58) where Richardson discloses an encrypted electronic identification key with biometric matching stored in memory.

With regard to claim 3 (Original), Richardson, Frederick, and Newton teach the process according to claim 1 or 2. Richardson teaches a process where the stored data records are logically separate from the biometric records (paragraph 42) where the records can be stored in one location.

With regard to claim 4 (Previously Presented), Richardson, Frederick, and Newton teach the process according to claim 1. Richardson teaches a process where the stored data records are physically separate from the biometric records (paragraph 42) where the records can be stored apart from one another.

With regard to claim 5 (Previously Presented), Richardson, Frederick, and Newton teach the process according to claim 1. Richardson teaches a process where the matching process includes generating a template image of the decoded captured biometric for matching against stored biometric records (paragraph 62) where Richardson discloses a digital identification techniques which includes recording an encrypted digital template.

With regard to claim 6 (Original), Richardson, Frederick, and Newton teach the process according to claim 5. Richardson teaches a process where the stored biometric records include a biometric enrol template of the left iris, a biometric enrol template of the right iris, and the identification code (paragraph 58) where Richardson discloses a biometric profile in which iris scanning is performed to identify a user.

With regard to claim 8 (Previously Presented), Richardson, Frederick, and Newton teach the process according to claim 1. Richardson teaches a process where the stored data records include a patient database (paragraph 33) and a prescriber database (paragraph 31 and 60).

With regard to claim 9 (Original), Richardson, Frederick, and Newton teach the process according to claim 8.

Frederick teaches a process where the stored data records further include a drug register database (column 19, line 53 through column 20, line 10) and a supplier database (column 19, line 53 through column 20, line 10).

Art Unit: 3626

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a process where the stored data records further include a drug register database and a supplier database as taught by Frederick, within the process of Richardson and Newton, with the motivation of providing a tool to manage the inventory of medicine and tracking who has dispensed the medicine (column 2, lines 33 – 65).

With regard to claim 10 (Currently Amended), Richardson, Frederick, and Newton teach the process according to claim 1. Richardson teaches a process further including the step of enrolling a patient into a program so that the patient is authorised to receive the substance (paragraphs 29, 30, and 32) where a fingerprint is used to identify a user, thus performing the act of enrolling or authorizing.

With regard to claim 12 (Currently Amended), Richardson, Frederick, and Newton teach the process according to claim 11.

Frederick teaches a process wherein prior to storing a biometric record of the captured biometric, the management computer performing a fraud check to ensure the patient is not already enrolled on the system (column 66, lines 34 – 47).

The motivation to combine the teachings of Richardson, Frederick, and Newton is discussed in the rejection of claim 9, and incorporated herein.

With regard to claim 13 (Currently Amended), Richardson, Frederick, and Newton teach the process according to claim 11 or claim 12. Richardson teaches a process wherein having decoded the captured biometric, the management computer transforming the captured biometric into an enrolment template in order to store a biometric record of the patient captured biometric (paragraphs 11, 28, 30, and 41).

With regard to claim 14 (Previously Presented), Richardson, Frederick, and Newton teach the process according to claim 1 or 11. Richardson teaches a process where the predetermined time is

Art Unit: 3626

determined according to the time required for the biometric capture process (paragraph 12) where the biometric matching is performed in less time as fewer matches are required.

With regard to claim 15 (Previously Presented), Richardson, Frederick, and Newton teach the process according to claim 1. Richardson teaches a process where the substance is a controlled substance (paragraphs 10 and 39).

With regard to claim 23 (Currently Amended), Newton, Richardson, and Frederick teach the system according to claim 18. Richardson teaches a process further comprising a firewall between the management computer and at least the capture apparatus (paragraphs 58 and 63).

Process, method, and system claims 11 and 16 – 22 repeat the subject matter of process claims 1, 3 – 4, and 8 – 9. As the underlying processes of claims 1, 3 – 4, and 8 – 9 have been shown to be fully disclosed by the teachings of Newton, Richardson, and Frederick in the above rejections of claims 1, 3 – 4, and 8 – 9; as such, these limitations (11 and 16 – 22) are rejected for the same reasons given above for claims 1, 3 – 4, and 8 – 9 and incorporated herein.

5. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Richardson et al., herein after Richardson (U.S. Publication Number 2003/0225596 A1) in view of Frederick (U. S. Patent Number 6,788,997) and Newton et al., herein after Newton (U.S. Patent Number 7,467,093) further in view of Meadows (U.S. Publication Number 2002/0116390 A1).

With regard to claim 7 (Currently Amended), Newton, Richardson, and Frederick teach the process according to claim 6.

Meadows' teaches a process where the stored biometric records further include a portrait image of the patient (paragraph 45). Although Meadows' invention is for the identification of dogs, the concept of adding a photo or portrait to the biometric record would be the same if applied to humans.



Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a process where the stored biometric records further include a portrait image of the patient as taught by Meadows, within the process of Newton, Richardson, and Frederick, with the motivation to provide a tool to aid and confirm the identification of a healthcare provider and/or patient (paragraph 9).

### ***Response to Arguments***

6. Applicant's arguments filed September 21, 2000 have been fully considered but they are not persuasive. Applicant's arguments will be addressed herein below in the order in which they appear in the response filed September 21, 2009.

In response to the Applicant's argument, it is respectfully submitted that the Examiner has applied new prior art to the amended claims. The Examiner notes that the amended limitations were not in the previously pending claims; as such, Applicant's remarks with the regard to the application of Richardson and Frederick are addressed in the above Office Action. In addition, regarding claim 1, the Applicant argues that the claimed method is directed to dispensing of pharmaceuticals directly to an authorized patient. The Examiner respectfully disagrees and submits amended claim 1 is directed to a method of obtaining patient authorization via biometric authorization; the substance, however, is not provided to the patient in the claim. The claim is merely reciting the steps to obtain biometric authorization.

### ***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action

Art Unit: 3626

is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTINE K. RAPILLO whose telephone number is (571)270-3325. The examiner can normally be reached on Monday to Thursday 6:30 am to 4 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Luke Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KKR

/C. Luke Gilligan/  
Supervisory Patent Examiner, Art Unit 3626